



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Karsten HENCO et al.

Serial No.: 08/157,195

Group Art Unit: 1807

Filed: December 8, 1993

Examiner: P. Tran

For: PROCESS FOR THE DETERMINATION OF IN VITRO AMPLIFIED NUCLEIC ACIDS

Hil (NE)
2/10/96
1041096

RESPONSE

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit the present response to the Office Action mailed April 29, 1996.

Applicants wish to thank Examiner Paul Tran for the courteous assistance extended to applicants' representative during an interview at the U.S. Patent and Trademark Office on August 6, 1996. Applicants also wish to thank the Examiner for express indication in the outstanding Office Action regarding previous rejections that no longer apply.

The claims stand rejected under 35 U.S.C. § 112, second paragraph. Reconsideration is respectfully requested.

The first reason put forward for the alleged indefinite claim language concerns the word "interacts" recited in the claims. Applicants respectfully submit that substituting the word -- hybridizes -- would be inappropriate; limiting the claims to a particular embodiment of a generic concept that comprising the invention. As disclosed in the present

specification, "interacts" represents a justifiable generic term. In addition to effecting hybridization, the embodiment of the presently claimed invention shown in Figure 2 demonstrates a substance, which interacts by *intercalating* with the nucleic acid to be analyzed. Limiting the claims to -- hybridizes -- would not include the embodiment of the presently claimed invention shown in Figure 2; thereby, unnecessarily limiting the present claims.

Applicants observe that intercalation is known in the art to represent a different process than hybridization. Hybridization defines the precise interaction between the nucleotides of a probe, on the one hand, with the complementary nucleotides of a nucleic acid, on the other. Intercalation defines a process, which effects a more-or-less known-specific substrate binding; for example, the binding of an ethidium bromide fluorescent dye to a nucleic acid. In accordance with the foregoing explanation, applicants respectfully submit that the generic term "interacts" is appropriate under the present circumstances.

With respect to the length of the nucleic-acid portion of the probe, applicants respectfully submit that no specific length need be recited in the claims. The functional language found in claim 68, (apparently, indicated by claim "58" in the statement of rejection), whereby the nucleic acid portion is defined as interacting with the nucleic acid to be analyzed, sufficiently defines the subject matter of the invention. One of ordinary skill in the art would readily appreciate the contents and length of the recited "nucleic acid portion" necessary to pair with the nucleic acid to be analyzed. Applicants understand that, pursuant to the aforesaid interview, it appears that the definition recited in claim 68 satisfies the requirements of 35 U.S.C. § 112, second paragraph.

Claims also stand rejected under 35 U.S.C. § 112, first paragraph. Reconsideration is respectfully requested.

Appearance of the term "the measurable signal is detected" was considered in the statement of rejection to include new matter. Applicants respectfully submit that no new matter is involved.

First of all, the presence of a "measurable signal" in claim 69 is readily deduced from the original claims. Original claim 1 recites "spectroscopically measurable parameters of said substance are subject to variation, creating a measurable signal" and "detection of the measurable parameter undergoing variation through the action of the gradient." Original claim 2 recites that "the spectroscopically measurable parameter ... is at least one luminescent or fluorescent dye" and "the denaturation condition is accompanied by a change in the spectroscopically measured signal." Original claim 3 recites that the "denaturation process is detected using wave length variation and/or shift in luminescence or fluorescence intensity."

Therefore, in accordance with original claims 1-3, there is provided: a luminescent or fluorescent dye as a spectroscopically measurable parameter that creates a measurable signal; nucleic-acid denaturation is accompanied by a change in the spectroscopically measured signal; which is detected by a variation or shift in luminescence or fluorescence intensity. In other words, the measurable signal is detected by a shift in luminescence or fluorescence intensity, as recited in present claim 69. "Satisfaction of the 'written description' requirement *does not* require *in haec verb* antecedence the originally filed application." *Staehelin v. Secher*, 24 USPQ 2d 1513, 1519 (BPA&I 1992), emphasis in

original. The question to be answered with respect to adequate descriptive support is whether the skilled artisan reading the specification (which includes the original claims) would understand that this specification describes the later claimed subject matter. *Freerksen v. Gass*, 21 USPQ 2d 2007 (BPA&I 1990). The specification need only expressly or *inherently* make clear to one of ordinary skill in the art what is later being claimed; the presence or absence of literal support in the specification not being the issue. *Ex parte Harvey*, 3 USPQ 2d 1626 (BPA&I 1987).

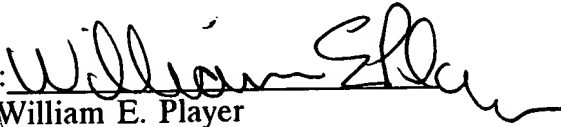
Concerning recitation of "at least one point mutation" in claim 72 is support in the specification at page 6 (first paragraph, line 6). Reciting "within the homogenous phase" in claim 75 is also recited in original claim 9. Reciting "excitation-effect emitting of electromagnetic radiation" in claim 80 is also recited in original claim 14 as "due to excitation, emitting electromagnetic waves." Reciting in claim 93 "having at least one non-naturally occurring chemical structural element" is supported in original claim 27.

Each of the instances of alleged indefinite claim language were discussed with the Examiner during the aforesaid interview. As a result of the interview, applicants understand that the Examiner agreed that the showing of support in the original disclosure was reasonably related to the language used in the present claims to warrant reconsideration.

Favorable action commensurate with the foregoing is requested.

Respectfully submitted,

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